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## LEGISLATION, REGULATIONS AND STANDARDS

## NRDC Calls on Federal Agencies to Ramp Up Seafood Safety Testing in Gulf

The Natural Resources Defense Council (NRDC) and nearly two dozen Gulf Coast organizations have <u>requested</u> that the Food and Drug Administration (FDA) and National Oceanic and Atmospheric Administration (NOAA) "strengthen the current protocols and data relied on to determine whether seafood is safe for consumption and when to re-open areas for fishing" after the massive oil spill that occurred in the Gulf of Mexico. Now that some fisheries have reopened, NRDC is concerned that existing testing and assessment protocols are insufficient to protect human health and safety. The organizations call for the agencies to include chemical monitoring in their seafood analyses, contending that cadmium, copper, lead, and mercury have all been detected in crude oil studies.

The August 17, 2010, letters request that the agencies (i) "ensure there is comprehensive monitoring of seafood contamination"; (ii) "ensure public disclosure of *all* seafood monitoring data and methods"; and (iii) "ensure that fishery re-opening criteria protect the most vulnerable populations including children, pregnant women, and subsistence fishing communities." Among other matters, NRDC notes, "The NOAA protocol for determining the conditions under which a fishery can be re-opened relies on an FDA risk assessment that fails to consider risks to the populations most vulnerable to seafood contamination."

According to NRDC, "[t]he FDA risk assessment uses the assumption that the 'average American' bodyweight is 176 lbs. This may be appropriate for adult men, but it will not protect smaller segments of the population." The organization also points to FDA's use of average consumption levels based on the national diet, which purportedly underestimates actual consumption in subsistence fishing communities. See NRDC Press Release, August 17, 2010.

In a related development, University of South Florida researchers have reportedly determined that the spilled oil has become toxic to marine organisms in Gulf spawning grounds. They apparently found widespread droplets of oil among the sediments of an underwater canyon important to the lifecycle of commercial fish species. The researchers also claim that phytoplankton, the microscopic plant-like organisms at the base of the marine food chain, was found to be in poor health. See The Los Angeles Times, August 18, 2010.



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SHB offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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#### Canada to Place BPA on List of Toxic Substances

Environment Canada has reportedly announced its intention to place bisphenol A (BPA) on the country's list of toxic substances within eight to 10 weeks, thus ending a regulatory process started in April 2008 when the government first banned polycarbonate baby bottles. According to a recently released letter from Environment Minister Jim Prentice, the agency has formally rejected the American Chemistry Council's July 15, 2009, request for a review board because the group purportedly did not supply "any new scientific data or information with respect to the nature and extent of the danger posed by bisphenol A." Environment Canada will provide opportunities for further comment under the Canadian Environmental Protection Act "following the publication of instruments for the preventive or control action of bisphenol A, such as a proposed regulation." See Postmedia News, August 17, 2010.

The news came shortly after Statistics Canada released a <u>study</u> examining lead and BPA concentrations in the Canadian population. Researchers used data from the 2007-2009 Canadian Health Measures Survey to determine that 91 percent of the population ages 6 to 69 had BPA in their urine "with a GM [geometric mean] concentration of 1.16  $\mu$ g/L (1.40  $\mu$ g/g creatinine)." In addition, the authors reported that "children aged 6 to 11 had significantly higher GM creatinine-standardized BPA concentrations than did other age groups."

These results were evidently comparable to the U.S. National Health and Nutrition Examination Survey, which detected BPA in 93 percent of Americans aged 6 or older. "The higher GM BPA concentrations in children may be due to food consumption in relation to their body weight," stated the study authors, who noted that their findings may also reflect "differences in absorption, distribution, metabolism, or excretion of BPA, creatinine metabolism or excretion, or the use of products containing BPA."

## **FSA Investigates Meat from Offspring of Cloned Cow**

The U.K. Food Standards Agency (FSA) has announced that meat from a cloned cow's offspring has evidently entered the food supply, sparking concerns about the country's livestock registration and tracking requirements. The agency apparently traced four female and four male calves to a cloned Holstein cow from the United States. According to FSA, farmers have not sold any milk from the three surviving females but have slaughtered the bulls and sold three for human consumption. "While there is no evidence that consuming products from healthy clones, or their offspring, poses a food safety risk, meat and products from clones and their offspring are considered novel foods and would therefore need to be authorized before being placed on the market," stated FSA in an August 11, 2010, news release, adding that food producers who purchased such animals or their offspring "will need to seek authorization under the Novel Food Regulations." See FSA News Release, August 4, 2010.

In response, the U.K. National Beef Association has asked FSA not to block products derived from clone offspring, including those with a cloned grand-parent in another country. As the association argued in an August 16, 2010,



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statement, a ban on these animals will deny U.K. livestock farmers "the advantages of breeding technology that is already used, without any market access restraint, in competing countries like the United States, and could eventually be taken up in almost all non-EU countries." See Food Politics, August 17, 2010.

Meanwhile, the Holstein UK breeding association and National Farmers Union Scotland have already criticized the Department for Environment, Food and Rural Affairs (Defra) over loopholes in its cattle traceability scheme. After *The Guardian* linked two of the bulls in question to a Scottish farm, the associations noted that current laws do not compel farmers to disclose information about cloned breeding stock when registering calves. In this case, however, the operation reportedly cleared the cattle with both the local agricultural department office and Holstein UK, in addition to registering the calves as clone progeny with the government. Defra Secretary of State Caroline Spelman has apparently pledged to look into the matter and to work with the European Union on procedural changes if necessary. *See The Guardian*, August 4, 2010.

The dustup has also gained traction in the United States, where *AlterNet* reporters spoke with the U.S. Department of Agriculture (USDA) about the potential for clones to infiltrate the American market. According to an August 20, 2010, article, one USDA spokesperson "said the department was 'not aware of an instance where a product from a cloned animal has entered the food supply' thanks to a 'voluntary moratorium'—but that offspring of clones, at the heart of the Europe scandal, 'are not clones and therefore not included' in the voluntary moratorium." Taking this statement to mean that Americans are also consuming "milk and meat from unlabeled clone offspring," *AlterNet* has called on its readers to question "the soundness of the clone process itself" and to demand labeling for these products.

#### LITIGATION

## Grocery Profit-Sharing Arrangement During Labor Strike Ruled Anticompetitive

The Ninth Circuit Court of Appeals has determined that an agreement among grocery chains in Southern California to share profits during an anticipated labor strike was anticompetitive in violation of the Sherman Act and rejected defendants' argument that the violation could be excused because the agreement was designed to be used as an economic weapon in a labor dispute. *California v. Safeway, Inc.*, Nos. 08-55671, 08-55708 (9th Cir., decided August 17, 2010). According to the court, despite the limited duration of the agreement and the fact that the groceries involved constituted, at most, 70 percent of the market, the agreement was anticompetitive because it removed all incentive to compete by providing lower prices or better service to consumers.

The court disagreed that the defendants needed the pact to effectively bargain with striking employees. In this regard, the court stated, "Defendants claim no purpose for their agreement beyond strengthening their hands in a labor dispute, so as to allow them to reduce the economic impact of a strike, a lawful tool of collective bargaining, and ultimately to be able to limit the wages and



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benefits of their employees. They do not assert that they could not reach an agreement with the unions without violating the antitrust laws—in fact, the history of multiemployer collective bargaining is to the contrary." A concurring and dissenting judge did not agree that the record was sufficient to conclude that the agreement violated the Sherman Act, saying it was not "intuitively obvious" that the agreement did so.

## Court Vacates APHIS Deregulation of GM Sugar Beets; No New Planting Allowed for Now

A federal court in California has decided to stop all new planting of genetically modified (GM) sugar beets in light of its September 2009 ruling that the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) violated environmental law when it deregulated the crop without conducting an appropriate environmental assessment. Ctr. for Food Safety v. Vilsack, No. 08-00484 (U.S. Dist. Ct., N.D. Cal., decided August 13, 2010). Additional information about the court's prior ruling appears in <a href="Issue 320">Issue 320</a> of this Update. While the court granted the plaintiffs' request to vacate APHIS's deregulation decision, it denied their motion for a permanent injunction.

The court determined that vacatur was justified because APHIS's errors were serious. "Moreover," the court observed, "APHIS's apparent position that it is merely a matter of time before they reinstate the same deregulation decision, or a modified version of this decision, and thus apparent perception that conducting the requisite comprehensive [environmental] review is a mere formality, causes some concern that Defendants are not taking this process seriously."The court also noted that APHIS had 10 months to take interim action since the court issued its ruling on the agency's violation of federal environmental laws, "but failed to act expediently."

Rejecting the economic consequences argument advanced by the government and the intervening defendants, the court stated, "it is not clear that economic consequences is a factor the Court may consider in environmental cases." The court also pointed out that its decision about the inadmissibility of a declaration by a defense expert left the defendants without evidence "that serious economic harm would be incurred pending a full environmental review or any interim action by APHIS."

A permanent injunction was not called for, according to the court, because, contrary to plaintiffs' contention, the possibility that the defendant-intervenors would violate the vacatur and that APHIS would be unable to enforce the "reinstated regulated status of genetically engineered sugar beets," was speculative. The denial was without prejudice, however, "if, after the deregulation decision is vacated. Plaintiffs can demonstrate that Defendant-Intervenors or other third parties have in fact violated the vacatur."

The remedy is limited to "any planting of genetically modified sugar beets after the date of this Order." The court would not allow destruction of GM crops that have already been planted and, in fact, will allow harvesting, processing and sale of all GM sugar beet root crops already planted. Given that the herbicide-



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resistant trait in sugar beets is present in 95 percent of the plants grown in the United States, this ruling could have a major impact on the industry. In fashioning its remedy, the court was careful to take into consideration Monsanto Co. v. Geertson Seed Farms, 130 S. Ct. 2743 (2010), thus allowing defendants to take interim measures, i.e., prepare an environmental impact statement (EIS) to meet their obligations under the law.

According to a news source, APHIS has apparently estimated that it could take until April 2012 to prepare an EIS on GM sugar beets. Industry officials have reportedly suggested that the agency has the authority to implement other measures to permit some planting of GM sugar beets, and a government spokesperson was quoted as saying the agency was "reviewing the judge's order in order to determine appropriate next steps." The organizations that brought the lawsuit called the ruling "a major victory for farmers, consumers and the rule of law. USDA has once again acted illegally and its approval of a biotech crop rescinded. Hopefully the agency will learn that their mandate is to protect farmers, consumers and the environment." See The New York Times, August 13, 2010; The Wall Street Journal and Earthjustice News Release, August 16, 2010.

## FTC Obtains Preliminary Injunction Against Internet Marketers Making Acai **Berry Health Claims**

The Federal Trade Commission (FTC) has taken action against companies that sell acai berry supplements, "colon cleansers" and other products online by featuring false Oprah Winfrey and Rachael Ray endorsements and illegally billing customer credit cards. According to an agency press release, a U.S. district court has temporarily ordered a halt to "an Internet sales scheme that allegedly scammed consumers out of \$30 million or more in 2009 alone through deceptive advertising and unfair billing practices." The court order also imposes an asset freeze and appoints a temporary receiver over several companies "while the FTC moves forward with its case to stop the company's bogus health claims and other deceptive and unfair conduct."

The companies purportedly made "free" trial offers for an acai berry supplement pitched as a rapid weight-loss product and a colon cleanser said to prevent cancer. The companies purportedly claimed that they would provide full refunds to unsatisfied customers. Apparently, the "free" trial required payment of a nominal sum and then "many consumers found it all but impossible to avoid paying full price for the products, typically \$39.95 to \$59.95" and were "automatically enrolled in a membership program and charged for additional monthly supplies of a product." The FTC estimates that "about a million people" fell victim to this scam involving "a product that didn't work in the first place." See FTC Press Release, August 16, 2010.

## Plaintiff Class Alleges POM Wonderful® Will Not Keep Consumers Young Forever

A putative class action has been filed against the maker of POM Wonderful® pomegranate (PWP) juice in a Florida state court, alleging that the company is misleading consumers by marketing its product "as having special health bene-



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fits, including but not limited to, the prevention, mitigation, and or treatment of the following: (a) atherosclerosis; (b) Blood Flow/Pressure; (c) Prostate Cancer; (d) Erectile Function; (e) cardiovascular disease; (f) Reduce LDL cholesterol; (g) and other age related medical conditions." Giles v. POM Wonderful, LLC, No. 10-32192 (Cir. Ct., 17<sup>th</sup> Jud. Cir., Broward County, Fla., filed August 6, 2010).

Seeking to represent a statewide class of consumers, the plaintiff claims, "In sum, the message is drink PWP and it will keep you young forever." According to the complaint, the company has no reasonable basis for making its health-related marketing claims and has, in fact, been warned by the Food and Drug Administration that the product's labeling directly violates federal law by establishing the product as a drug. The plaintiff also alleges that the National Advertising Division of the Council of Better Business Bureaus found the defendant's medical research inadequate to substantiate some of its purported health benefits, and the U.K.'s Advertising Standards Authority determined that the company's evidence fell short and thus, it was making "misleadingly exaggerated" healthbenefit claims.

The plaintiff alleges violations of Florida's Deceptive and Unfair Trade Practices Act and breach of express warranty; she seeks restitution, disgorgement, declaratory and injunctive relief, a corrective advertising campaign, costs, and attorney's fees. She contends that no individual plaintiff's claim exceeds \$75,000 and appears to base her damages on paying "a significant price premium" for a product that cannot deliver the benefits the defendant has promised.

## Restaurant Workers Sue Mario Batali and Joseph Bastianich

Renowned restaurateurs Mario Batali and Joseph Bastianich have reportedly been sued by workers in their East and West Coast restaurants. A complaint filed in late July 2010 by current and former employees of New York City's Babbo Ristorante e Enoteca was amended to include a class of employees who work in five additional east coast eateries.

They reportedly allege that the Batali-Bastianich enterprise "unlawfully confiscated a portion of their workers' hard-earned tips in order to supplement their own profit. At the end of every shift, instead of distributing customers' credit card tips to the workers who earned them as the law requires, Mr. Batali, Mr. Bastianich, and their restaurants took from the tip pool an amount equal to approximately 4-5% of the restaurants' wine sales (and sometimes other beverage sales) for the night and put it in their own pockets."

The New York plaintiffs are apparently seeking class certification and the recovery of minimum wages, overtime, misappropriated tips, and "spreadof-hours pay." A lawyer for the plaintiffs was quoted as saying, "Mr. Bastianich and Mr. Batali are not above the law. It is a stunning response to a lawsuit to announce to the world a commitment to fight one's employees to the end. At some point, we hope the restaurant owners will learn that service employees also have rights, and they are fully able to vindicate them." Batali has reportedly said, "I would love to come back with a ruling from a judge and have them throw [the lawsuit] out. We're going to fight this to every inch of the law, because



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we know we're right. We're not going to let them shake us down for a quick settlement."

According to a news source, a second lawsuit was filed in August in Los Angeles Superior Court by a former server and a bartender at Pizzeria Mozza. They claim that the defendants take 5 percent of the employees' tips, refuse to allow workers to take rest and meal breaks and do not pay wages promptly when employees are terminated. See DNAinfo.com, Forbes.com, July 30, 2010; The Los Angeles Times and Courthouse News Service, August 17, 2010.

## Parents Sue Online Companies for Spying on Kids

A lawsuit filed in a federal court in California by a putative class of parents on behalf of their children alleges that Clearspring Technologies, Inc. and other companies used an online tracking device that enabled their Websites to access and disclose users' online activities and personal information. White v. Clearspring Techs., Inc., No. 10-5948 (U.S. Dist. Ct., C.D. Cal., filed August 10, 2010). Based on research conducted at the University of California, Berkeley, the complaint alleges that the companies install a Flash cookie on user computers without the users' knowledge or consent, and the cookie can re-spawn itself even when users regularly delete their cookies.

According to the research article, the "top 100 websites are using Flash cookies to 'respawn,' or recreate deleted HTTP cookies. This means that privacy-sensitive consumers who 'toss' their HTTP cookies to prevent tracking or remain anonymous are still being uniquely identified online by advertising companies. Few websites disclose their use of Flash in privacy policies." Ashkan Soltani, et al., "Flash Cookies and Privacy," August 10, 2009). The information obtained by the defendants allegedly allows advertisers to "observe the user's browsing behavior across many websites ... and thereby acquire extensive behavioral data."The plaintiffs allege that some cookies "record a wide array of user-profiling information, IP numbers, shopping cart contents, user IDs, user-selected preferences, serial numbers, frequencies of contacts with companies, demographics, purchasing histories, credit-worthiness, social security numbers and other personal identifiers, credit card numbers, phone numbers, and addresses."

Claiming that these data collection practices harmed the finite resources of their computers, the plaintiffs seek certification of a nationwide class. They allege violations of the federal Computer Fraud and Abuse Act and California's Computer Crime Law, Invasion of Privacy Act, Consumer Legal Remedies Act, and Unfair Competition Law, as well as trespass to personal property and unjust enrichment. The plaintiffs' claim damages in excess of \$5 million and seek injunctive relief; statutory, compensatory and punitive damages, restitution, costs, and attorney's fees.

## Chicago Jury Awards \$30.4 Million to Diacetyl-Exposed Factory Worker

According to a news source, a man who worked in a Chicago-area plant for eight years and was diagnosed with bronchiolitis obliterans has been awarded



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\$30.4 million on claims that workplace exposure to the butter-flavoring chemical diacetyl left him with 25 percent of normal lung capacity that will require a lung transplant within the next 10 years. *Solis v. BASF Corp.*, No. n/a. The largest verdict previously awarded in a similar case was \$20 million to a former popcorn plant worker in Missouri. Plaintiff Gerardo Solis, 45, was represented by Independence, Missouri, attorney Ken McClain. *See The Joplin Globe*, August 16, 2010.

### OTHER DEVELOPMENTS

### **Premature Development Causes Unease in China**

Chinese health experts have reportedly estimated that "at least 30,000 children developed early maturity" in Shanghai alone, raising concerns about food additives and pesticides allegedly laden with sex hormones. According to an August 18, 2010, *China Daily* article, one doctor with the Beijing Maternal and Child Healthcare Hospital has suggested that "early maturity in Chinese children is as high as 1 percent, nearly 10 times the rate in most Western countries." The physician apparently attributed the condition "to the rising amount of estrogen in the food chain as the result of pesticides being sprayed on fruit and vegetables."

Although *China Daily* noted the 2009 Food Safety Law and other attempts to regulate food additives, it also suggested that enforcement has been difficult if not "impossible." As one researcher with the Chinese Center for Disease Control and Prevention purportedly said, "China has 200 million scattered rural households that produce food, and has more than 500,000 small and medium food processors."

Meanwhile, U.S. Food and Drug Administration (FDA) Commissioner Margaret Hamburg has apparently praised China's recent efforts to improve its food safety record. Speaking after her first visit to the FDA inspection post in Beijing, Hamburg reportedly lauded the agency's work with Chinese officials to safeguard products exported to the United States. "We will never have the resources, human or financial, to inspect all these facilities on a regular basis so we are working through bilateral multilateral arrangements and try to share information and harmonize standards and approaches in ways that benefit all of us as a global community of regulators," she was quoted as saying. See The Associated Press, August 13, 2010; The Wall Street Journal, August 15, 2010.

### Royal Society Papers Suggest Innovative Solutions to Looming Food Shortages

The U.K. Royal Society has published 21 papers addressing concerns that climate change, water shortages and increased demand will disrupt the global food supply in coming decades. Titled *Food Security: Feeding the World in 2050*, the compendium challenges citizens, politicians and scientists "to increase food production, but to do so in a way that is sustainable, reducing our greenhouse gas emissions and preserving biodiversity." To meet these objectives, the papers recommend several low-tech solutions, such as better storage facilities to reduce food waste, as well as novel technologies. The latter include (i) artificial



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meat "grown in a vat," and (ii) increased use of nanotechnology, which paper author Philip K. Thornton said "is expected to become more important as a vehicle for delivering medication to livestock." As Chief Scientific Advisor John Beddington urges in the volume's preface, "The need for action is urgent given the time required for investment in research to deliver new technologies to those who need them, and for political and social change to take place." See The Guardian, August 16, 2010.

## SCIENTIFIC/TECHNICAL ITEMS

## Study Alleges Link Between Diet Soft Drinks and Premature Births

A recent study has purportedly linked consumption of carbonated diet sodas with an increased risk of premature birth. Thorhallur Halldorsson, et al., "Intake of artificially sweetened soft drinks and risk of preterm delivery: a prospective cohort study of 59,334 Danish pregnant women," American Journal of Clinical *Nutrition*, June 30, 2010. Researchers evaluated data from approximately 60,000 pregnancies tracked in Denmark between 1996 and 2002. According to the study, women in the middle of their pregnancies who drank at least one diet soft drink daily were 38 percent more likely to have a premature baby before 37 weeks of pregnancy than those who abstained. In addition, women who drank at least four such products per day were at a 78 percent risk of early delivery.

The researchers claimed that "no association was observed for sugarsweetened carbonated soft drinks or for sugar-sweetened noncarbonated soft drinks" and suggested that more studies are needed to reject or confirm their findings. Halldorsson told a news source that "it may be non-optimal" for pregnant women to drink artificially sweetened beverages in high amounts. Although the study did not evaluate specific artificial sweeteners, Halldorsson cited indirect evidence linking aspartame to premature births in animals. See Reuters, July 26, 2010.

### U.S. Researchers Claim That Overweight Youth Are Getting Heavier

Overweight Americans ages 2 to 19 have become heavier over the last decade, according to a newly published study. May Beydoun & Youfa Wang, "Sociodemographic disparities in distribution shifts over time in various adiposity measures among American children and adolescents: What changes in prevalence rates could not reveal," International Journal of Pediatric Obesity, August 2010. Conducted by researchers at Johns Hopkins Bloomberg School of Public Health and the National Institute on Aging, the study used population data from the National Health and Nutrition Examination Survey to examine changes in the body mass index (BMI), waist circumference (WC) and triceps skinfold thickness (TST) of boys and girls across socio-demographic groups.

According to Wang, the data showed significant weight gains that were "unequally distributed" across the demographic groups and spectrums of BMI,



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WC and TST. "Heavier children and adolescents gained more adiposity, especially waist size, and these findings were most significant among children ages 6 to 11," he said in a statement. "Ethnic disparities in mean BMI have also increased substantially when comparing black girls with their white counterparts for all ages combined."

Beydoun also noted that U.S. children and youth "may be at greater obesity-related risks than what was revealed by increases in BMI, as waist circumference is a better predictor of future health risks, such as for type 2 diabetes and heart disease in adults. More vigorous efforts should be made to understand the underlying causes. Moving forward, this could help guide future population-based interventions including those focusing on the total population and those targeting vulnerable or genetically susceptible groups." See Johns Hopkins Bloomberg School of Health Press Release, August 18, 2010.

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## **FOOD & BEVERAGE LITIGATION UPDATE**

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

SHB attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.



